DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Denver District Office
Building 20 – Denver Federal Center
P.O. Box 25087
Denver, Colorado 80225-0087
TELEPHONE: 303-236-3000

January 24, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Andy J. Vaz
Partner
Vaz Dairy
3835 E. McGaffey
Roswell, NM 88201

PURGED

Ref. #. – DEN-00-16

Dear Mr. Vaz,

An investigation of your dairy farm operations located at 3835 E. McGaffey, Roswell, NM, was conducted by Food and Drug Investigator Betty Kay Baxter on December 1 - 2, 1999. That inspection confirmed that you offered animals for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, you sold a cow on September 13, 1999 at [redacted] which was subsequently slaughtered for food and found to contain illegal levels of drug residues by USDA testing. These incidents were recorded under USDA case # 99-0755-NM:

> **September 14, 1999** USDA analysis of tissue samples collected from your animal (USDA Sample #400024) identified the presence of a Gentamicin residue of [redacted] ppm in the kidney. No tolerance has been established for residues of Gentamicin in the edible tissues of dairy cattle in Title 21 Code of Federal Regulations, Part 556.300 (21 CFR 556.300).

Our investigation revealed the use of BS-Clear (Gentamicin Sulfate, Dexamethazone, and Neomycin) to treat this cow. The presence of Gentamicin drug at the levels found in edible tissues from this animal cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

BS-Clear was used in an extra-label manner. There are limitations and conditions established for extra-label drug use or intended extra-label drug use in animals (21 CFR 530 – Extra-label Drug Use in Animals), a copy of which is enclosed with this letter. You should review all your drug use practices to assure you are compliant with 21 CFR 530.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you or under your direction have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissues. The food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended as an all-inclusive list of violations. As a dairy farm operator and owner/seller of medicated animals for food use, you are responsible for assuring that your overall operation and the products you distribute are in compliance with the law. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies. To avoid future illegal residue violations you should take precautions such as:

1) Implement a system to withhold a medicated animal from slaughter for food for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal, then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

2) Implement a system for medical treatment records that include: drug used, treatment period, who administered the drug, amount administered, appropriate withdrawal period and the animal's identification.

3) Implement a system for drug use, including extra-label use which is only authorized by a veterinarian, and storage to prevent inappropriate access and use.

You should notify this office in writing within 15 working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Betty Kay Baxter, Acting Compliance Officer, at the above address. If you have questions regarding this letter you may contact Ms. Baxter at (303) 236-3084.

Sincerely,

Janis V. Halvorsen

Janis V. Halvorsen
Acting Distract Director

Enclosure:
As Stated